IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

1st Named Inventor:	Lucien A. Couvillon, Jr.
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Title:	External counterpulsation device using electroactive polymer actuators
Art Unit:	3764
Examiner:	Agarwal, Manuj
Docket No.:	S13.12-0146 (now 02-377)
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PETITION UNDER 1.136(a) AND

APPEAL BRIEF UNDER 37 C.F.R. §41.37

Applicants hereby petition the Assistant Commissioner to grant a one month extension of time, up to and including Wednesday, March 14, 2007. The extension fee in the amount of $120.00 may be charged to deposit account No. 50-1047. In addition, any deficiencies may be charged to deposit account No. 50-1047.

As set forth in the Notice of Appeal filed by first-class mail on December 11, 2006 and received by the Patent and Trademark Office on December 14, 2006, appellant hereby appeals the final decision of the Examiner in the above-identified application rejecting claims 1-35.

Appellants respectfully request that the Board of Patent Appeals and Interferences reverse the Examiner's rejection of the claimed subject matter.

I. REAL PARTY IN INTEREST

Boston Scientific Scimed, Inc. is the assignee of the present invention and the real party in interest.

II. RELATED APPEALS AND INTERFERENCES

No prior and pending appeals, judicial proceedings or interferences are known to the appellant, which may be related to, directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

III. STATUS OF CLAIMS

The presently pending claims are claims 1-35. Claims 1-35 are rejected.

A copy of claims 1-35 is provided in the attached Appendix.

IV. STATUS OF AMENDMENTS

A final Office Action was mailed on August 11, 2006, rejecting Claims 1-35. A response was filed subsequent to the Final Office Action on October 11, 2006, and in an Advisory Action mailed on October 25, 2006, the Examiner indicated that the request for reconsideration was considered but did not place the application in condition for allowance. A Notice of Appeal was filed by first-class mail on December 11, 2006 and received by the Patent and Trademark Office on December 14, 2006.

The claims have not been amended subsequent to the final rejection.

V. SUMMARY OF CLAIMED SUBJECT MATTER

The invention is adequately described in independent claims 1, 18 and 25, the only independent claims, and claims 10-14, 28 and 29, which have been argued separately.

Claim 1 is directed to a system for exerting a compressive force on an exterior treatment portion of a user's body in synchrony with the heart beat of the user, comprising: (a) a covering member for covering the treatment portion; and (b) an electroactive polymer (EAP) actuator operably connected to the covering member, wherein the electroactive polymer actuator comprises an electroactive polymer member, a counter electrode and an electrolyte-containing region disposed between the electroactive polymer member and the counter electrode. See, e.g.,

original claim 1 and the specification at page 1, lines 4-12, page 3, lines 2-5 and 23-27, and page 11, lines 12-19.

Dependent claim 10 is directed to a system like that of claim 1, and which further comprises: (a) a heart sensor sensing a sinus rhythm of the heart and providing a heart sensor signal indicative of the sinus rhythm; (b) a controller operably coupled to the EAP actuator configured to provide a drive signal, based on the heart sensor signal, to drive actuation of the EAP actuator, wherein the covering member is flexible such that actuation of the EAP actuator drives deformation of the covering member, and (c) a feedback component sensing a feedback characteristic and providing a feedback signal indicative of the sensed feedback characteristic. See, e.g., original claims 6-10. See also, e.g., the specification at page 2 line 27 to page 3, line 5, page 7, lines 5-20, page 9, lines 22-26, page 10, lines 16-21, page 11 lines 6-15.

Dependent claim 11 is directed to a system like that of claim 10, and further wherein the controller is configured to provide the drive signal based on the feedback signal. See, e.g., original claim 11 and the exemplary embodiments described the specification at page 10, lines 22-27 and page 12, lines 4-12.

Dependent claim 12 is directed to a system like that of claim 11, and further wherein the feedback component comprises a metabolic sensor sensing a metabolic characteristic and providing the feedback signal based on the metabolic characteristic. See, e.g., original claim 12. See also, e.g., the specification at page 10, line 27 to page 11, line 3.

Dependent claim 13 is directed to a system like that of claim 11, and further wherein the feedback component comprises a blood flow sensor. See, e.g., original claim 13. See also, e.g., the originally filed specification at page 10, line 27 to page 11, line 3.

Dependent claim 14 is directed to a system like that of claim 11, and further wherein the feedback component comprises a blood pressure sensor. See, e.g., original claim 14. See also, e.g., that specification at page 10, line 27 to page 11, line 3.

Independent claim 18 is directed to a counterpulsation apparatus, comprising: a garment; and an electroactive polymer (EAP) actuator connected to the garment, wherein the electroactive polymer actuator comprises an electroactive polymer member, a counter electrode and an electrolyte-containing region disposed between the electroactive polymer member and the counter electrode. See, e.g., original claim 18 and the specification at page 3, lines 23-27 and page 6, lines 14-20.

Independent claim 25 is directed to a method of exerting pressure on an external treatment area of a patient, comprising (a) providing a garment to cover the treatment area; and (b) actuating electroactive polymer (EAP) actuators connected to the garment in synchrony with the heart beat of the user, wherein the electroactive polymer actuators comprise an electroactive polymer member, a counter electrode and an electrolyte-containing region disposed between the electroactive polymer member and the counter electrode. See, e.g., original claim 25 and the specification at page 1, lines 4-12, page 3, lines 23-27, page 7, lines 13-18, and page 11, lines 12-19.

Dependent claim 28 is directed to a method like that of independent claim 25, but further comprises (a) sensing a heart beat of the patient and providing a heart beat sensor signal indicative of the sensed heart beat, (b) actuating the EAP actuators to exert counterpulsation pressure based on the heart beat sensor signal, and (c) sensing a biological characteristic indicative of an efficaciousness of the counterpulsation pressure and providing a biological sensor signal indicative of the sensed characteristic. See, e.g., original claims 26-28. See also, e.g., the specification at page 2 line 27 to page 3, line 10, page 6, lines 14-20, page 8, lines 10-15 page 9, lines 22-29 and page 10, line 16 to page 11, line 3.

Dependent claim 29 is directed to a method like that of dependent claim 28, in which actuating the EAP actuators comprises actuating the EAP actuators based on the biological sensor signal. See, e.g., original claim 29. See also, e.g., the specification at page 10, line 22 to page 11, line 3, and page 12, lines 4-9.

Advantages of the claimed invention relative to the prior art include the following, among others:

The actuators in prior art exterior counter pulsation (ECP) systems generally are pneumatic. See e.g., page 2, lines 3-17 of the originally filed specification. They were typically rather large and bulky leading to a clumsy fit around the patient. *Id.* In addition, the large pneumatic actuators were typically quite noisy and difficult to control in precise synchrony with the heartbeat. *Id.* Further, the actuators were quite expensive, mechanically inefficient and required a bulky, complex pneumatic drive console. *Id.*

Attempts to utilize electro-reactive polymer gels (as in Brown US 6,123,681 discussed below, for example) as actuators in ECP systems were partially successful in overcoming the above stated problems. However, electroactive polymer actuators (EAPs) of the type recited in

the appealed claims, for example, are more efficient and provide greater flexibility in the placement and control of the counterpulsation forces. See, e.g., page 12, lines 20-26 of the originally filed specification. Also, the relatively low activation voltage and high efficiency of those EAPs allow the use of simple, small drive and monitoring circuits, such as those found in personal computer card interfaces. *Id.*

VI. GROUNDS OF REJECTION TO BE REVIEWED UPON APPEAL

The following grounds of rejection are presented for review:

The rejection of claims 1-35 under 35 U.S.C. 103(a) as being unpatentable over Brown US 6,123,681 in view of Shabty et al. US 2005/0137507 (Shabty), Madden et al. US 6,249,076 (Madden), and Hegde et al. US 2004/0230090 (Hegde).

The provisional rejection of claims 1-14, 16 and 17 for double patenting of the obviousness type over claims 1-15 of copending Application No. 10/373,940.

The provisional rejection of claims 15 and 18-29 for double patenting of the obviousness type over claims 1-15 of copending Application No. 10/373,940 in view of Brown and Shabty.

VII. ARGUMENT

The following legal authorities are relied on in the following argument in the order in which they are cited:

MPEP 2142, second paragraph,

Akzo N.V. v. U.S. International Trade Commission, 808 F.2d 1241, 1480-81, 1 U.S.P.Q.2d, 1241, 1246 (Fed. Cir. 1986), *cert. denied,* 482 U.S. 909 (1987),

Loctite Corp. v. Ultraseal Ltd., 781 F.2d 861, 874, 228 U.S.P.Q. 90-99 (Fed. Cir. 1985),

In re Jones, 958 F.2d 347, 351, 21 U.S.P.Q.2d 1941, 1943-44 (Fed. Cir. 1992),

In re Fine, 837 F.2d 1071, 1075, 5 U.S.P.Q. 1596, 1598-99 (Fed. Cir. 1988),

MPEP 2143.02 and the cases cited therein,

King Instrument Corp. v. Otari Corp., 767 F.2d 853, 226 U.S.P.Q. 402 (Fed. Cir. 1985),

Wang Laboratories, Inc. v. Toshiba Corp., 993 F.2d 858, 26 U.S.P.Q.2d 1767 (Fed. Cir. 1993),

MPEP 804.II.B.1 and the cases cited therein, and

706.02(j).

The References:

Brown

Brown discloses anti-embolism stockings controlled by polymer strips. The polymer strips contract upon electrical stimulation, thereby causing compression to be exerted upon a portion of the body. Electroactive polymer (EAP) actuators of the type recited in the appealed claims are not disclosed in Brown, nor is the ability to function in synchrony with the heartbeat of the user.

Shabty

Shabty discloses inflatable cuffs or a plurality of inflatable cuffs for counterpulsation therapy without the use of compressed air. The inflatable cuffs of Shabty are completely different from the stockings of Brown in appearance (cuffs vs. stockings), basis of operation (inflation vs. material constriction), and purpose of operation (counterpulsation therapy vs. embolism prevention). The cuffs are not controlled by EAPs of any type.

Hegde

Hegde disclose a vascular assist device which increases blood flow, generally in the aorta, by alternately compressing and releasing it. The device comprises at least a cuff usually assisted by a bladder. The disclosure of Hegde relates to an entirely different type of device from those of Brown and Shabty (and the present claims). The device of Hegde is implanted in the body of a patient and does not provide counterpulsation by operating on a limb.

Madden

Madden discloses electroactive polymer actuators of the type recited in the present claims. However, the only possibly practical application disclosed in Madden involves the use of a maximum number of two actuators to turn a bearing in an unspecified mechanical device. See Figures 5 and 6 and their explication at columns 7 and 8. There is no suggestion of how the disclosed actuators could be used in any greater number in an anti-embolism stockings such as those disclosed by Brown.

The Rejections

A. Claims 1-35 over Brown, Shabty Madden and Hegde-Obviousness

Claims 1-35

As described above, Brown discloses anti-embolism stockings controlled by polymer strips. The type of actuator required by the instant claims (i.e., an electroactive polymer actuator comprising an electroactive polymer member, a counter electrode and an electrolyte-containing region disposed between the electroactive polymer member and the counter electrode) is nowhere disclosed in the Brown patent.

Brown is also silent with regard to the ability of the disclosed stockings to function in synchrony with the heartbeat of the user.

The Examiner has stated that the Brown teaching of sequential compression is "clearly" for "synchronized compressions." That statement is erroneous. The sequential compressions in Brown are necessary to "mimic the pulsatile milking action of leg muscles" lacking in the prior art at that time. Compare column 3, lines 30-33, with column 1, lines 54-58. It is not disclosed, nor does it appear necessary, for the sequential pulsation to be synchronous with heartbeat to provide the anti-embolism effect desired by Brown.

The Examiner has relied on Madden for a teaching of the type o of EAP recited in the appealed claims. He has urged that (1) "Brown isn't restricted to any specific type of EAP actuator" and that (2) "any conventional actuator would work."

Assertion (1) is simply erroneous, an error of fact. Brown discloses suitable polymer materials, for instance, at column 3, lines 3-12, column 4, lines 26-42 and 53 to 57. Brown is limited to polymers, particularly polymer strips, which can contract upon the application of a stimulus, particularly an electrical stimulus that is supplied by wires that are connected to the polymer strips. The Brown disclosure does not encompass the type of actuator required by the appealed claims.

Assertion (2) is an error of law. The Brown disclosure does not state, or suggest in any manner, that "any conventional actuator would work." That conclusion is the Examiner's, and is based on a hindsight consideration of Brown and Madden. See MPEP 2142, second paragraph. See also *Akzo N.V. v. U.S. International Trade Commission*, 808 F.2d 1241, 1480-81, 1

U.S.P.Q.2d, 1241, 1246 (Fed. Cir. 1986), *cert. denied,* 482 U.S. 909 (1987), *Loctite Corp. v. Ultraseal Ltd.*, 781 F.2d 861, 874, 228 U.S.P.Q. 90-99 (Fed. Cir. 1985).

Madden discloses electroactive polymer actuators of the type recited in the present claims. However, the possibly practical application disclosed in Madden involves the use of a maximum number of two actuators to turn a bearing in an unspecified mechanical device, and since there is actually no specific practical application disclosed, there is no suggestion of how the disclosed actuators could be used in any greater number in anti-embolism stockings such as those disclosed by Brown or claimed here.

To restate for emphasis, only with the use of undue hindsight would one of ordinary skill in the art have been led to incorporate the actuators of Madden into the anti-embolism stockings of Brown. More fundamentally, there is no suggestion or motivation to be found in the references themselves for their combination, particularly with any reasonable expectation of success. *In re Jones*, 958 F.2d 347, 351, 21 U.S.P.Q.2d 1941, 1943-44 (Fed. Cir. 1992), *In re Fine*, 837 F.2d 1071, 1075, 5 U.S.P.Q. 1596, 1598-99 (Fed. Cir. 1988). Also see MPEP 2143.02 and the cases cited therein.

The Examiner has relied on Shabty as a disclosure of counterpulsation therapy in synchrony with the heartbeat of the user. See paragraph [0014]. In contrast, Brown is not directed to counterpulsation therapy. Rather, Brown is directed to embolism prevention. In addition to that difference in purpose, the cuffs of Shabty are completely different from the stockings of Brown in structure (i.e., cuffs as opposed to stockings) and basis of operation (i.e., inflation by compressed air opposed to constriction of the material per se with no inflation). Incorporation of this reference into the combination further highlights the use of undue hindsight in view of appellant's own disclosure.

The Examiner has relied on Hegde for an additional disclosure of synchrony of counterpulsation with heartbeat. However, as described above, the disclosure of Hegde relates to an entirely different type of device from those of Brown and Shabty. The device of Hegde is implanted in the body of a patient and does not provide therapy by operating on a limb.

As discussed above, Brown relates to anti-embolism therapy, Shabty to counterpulsation. Hegde relates to vascular (generally aortic) assist therapy, i.e., blood flow improvement. A patient requiring the Hegde therapy is one suffering from congestive heart failure. See Background. A patient requiring the use of the Brown device is an immobilized patient with a

tendency to develop thrombophlebitis with formation of intravascular thrombi. See Background of the Invention. The purpose of the Shabty device is "to relieve angina pectoris, to raise cardiac output" and "to enhance renal, cardiac and cerebral circulation." See the paragraph [0002].

The references are directed to the treatment of different conditions using diverse and disparate types of devices. As pointed out with respect to Brown, Shabty and Madden, the application of undue hindsight in constructing the rejection is apparent. The addition of Hegde to the mélange of references further emphasizes the undue hindsight, particularly because of its quite different structure and function. *King Instrument Corp. v. Otari Corp.*, 767 F.2d 853, 226 U.S.P.Q. 402 (Fed. Cir. 1985). Even if one were to consider that Brown, Shabty and Hegde all related to blood flow broadly, that alone would not necessarily make them properly combinable, in view of the numerous significant differences between them. *Wang Laboratories, Inc. v. Toshiba Corp.*, 993 F.2d 858, 26 U.S.P.Q.2d 1767 (Fed. Cir. 1993).

For at least the above reasons, it is respectfully submitted that independent claims 1, 18 and 25, as well as claims 2-17, 19-24 and 26-36 depending therefrom, are patentable over Brown, Shabty, Madden and Hegde.

Claim 10

In addition to (a) the features of claim 1, distinguished above, (b) a heart sensor sensing a sinus rhythm of the heart and providing a heart sensor signal indicative of the sinus rhythm, and (c) a controller, operably coupled to the EAP actuator, which provides a drive signal to drive actuation of the EAP actuators based on the heart sensor signal, claim 10 further comprises a feedback component sensing a feedback characteristic and providing a feedback signal indicative of the sensed feedback characteristic.

The Examiner has not pointed out how the additional introduction of this feedback component is obvious in view of Brown, Shabty, Madden and Hegde. See 706.02(j) Contents of a 35 U.S.C. 103 Rejection. Moreover, it is respectfully submitted that the combination of features described in claim 10 are not taught or suggested by these this combination of references.

Claim 11

Claim 11 has all the limitations of claim 10 and further requires that the controller be configured to provide a drive signal based on the feedback signal.

The Examiner has not pointed out how the additional introduction of this feature is obvious in view of Brown, Shabty, Madden and Hegde, and is respectfully submitted that the combination of features described in claim 11 are not taught or suggested by this combination of references.

Claim 12

Claim 12 has all the limitations of claim 11 and further requires that the feedback component comprise a metabolic sensor sensing a metabolic characteristic and providing the feedback signal based on the metabolic characteristic.

The Examiner has not pointed out how the additional introduction of this feature is obvious in view of Brown, Shabty, Madden and Hegde, and is respectfully submitted that the combination of features described in claim 12 are not taught or suggested by this combination of references.

Claim 13

Claim 13 has all the limitations of claim 11 and further requires that the feedback component comprise a blood flow sensor.

The Examiner has not pointed out how the additional introduction of this feature is obvious in view of Brown, Shabty, Madden and Hegde, and is respectfully submitted that the combination of features described in claim 13 are not taught or suggested by this combination of references.

Claim 14

Claim 14 has all the limitations of claim 11 and further requires that the feedback component comprise a blood pressure sensor.

The Examiner has not pointed out how the additional introduction of this feature is obvious in view of Brown, Shabty, Madden and Hegde, and is respectfully submitted that the

combination of features described in claim 14 are not taught or suggested by this combination of references.

Claim 28

In addition to a method requiring (a) the features of claim 25, distinguished above, (b) sensing a heart beat of the patient, (c) providing a heart beat sensor signal indicative of the sensed heart beat, and (d) actuating the EAP actuators to exert counterpulsation pressure based on the heart beat sensor signal, claim 28 also requires sensing a biological characteristic indicative of an efficaciousness of the counterpulsation pressure and providing a biological sensor signal indicative of the sensed characteristic.

The Examiner has not pointed out how the further introduction of these features is obvious in view of Brown, Shabty, Madden and Hegde, and is respectfully submitted that the combination of features described in claim 28 are not taught or suggested by this combination of references.

Claim 29

In addition to the features of claim 28, claim 29 requires that actuation of the EAP actuators be based on the provided biological sensor signal.

The Examiner has not pointed out how the additional introduction of this feature is obvious in view of Brown, Shabty, Madden and Hegde, and it is respectfully submitted that the combination of features described in claim 29 does not appear to be taught or suggested by this combination of references.

B. Claims 1-29 over the claims of Serial No. 10/373,940, alone or in view of Brown and Shabty-Double Patenting

Claims 1-14, 16 and 17 have been finally rejected under the doctrine of "double patenting of the obviousness type" over the claims of copending Application Serial No. 10/373,940. Claims 15 and 18-29 have been similarly finally rejected over the claims of the copending application in view of Brown and Shabty. These rejections are now moot in view of the amendment of copending Application Serial No. 10/373,940.

The broadest claims in SN 10/373,940 as amended are reproduced below.

1. A system for assisting coronary circulation of a heart, comprising:
a compressor adapted to be placed adjacent to an epicardial wall of the heart;
and an electroactive polymer (EAP) actuator coupled to the compressor, wherein the EAP actuator comprises: a plurality of EAP actuator members disposed about a periphery of the compressor and an electrical driver operably connected to the EAP actuator receives a plurality of signals from a computing device and provides a plurality of driving signals driving actuation of the plurality of EAP actuator members at coordinated intervals such that the *EAP actuator member situated closest to an apex of the heart contracts first*, followed by the sequential contraction of the EAP actuator members respectively farther from the apex such that a propagation-pulsing action of the heart is achieved.

21. A method of assisting coronary circulation of a heart, comprising:
placing the heart in a compressor placed proximate to an epicardial wall of the heart, wherein the compressor comprises a flexible receiver having an electroactive polymer (EAP) actuator disposed thereon, wherein the EAP actuator comprises a plurality of EAP actuator members disposed about a periphery of the compressor;
providing a plurality of electrical driving signals to the EAP actuator from an electrical driver operably connected to the EAP actuator, wherein the electrical driver receives a plurality of signals from a computing device driving actuation of the plurality of EAP actuator members at coordinated intervals *such that the EAP actuator member situated closest to an apex of the heart contracts first*, followed by the sequential contraction of the EAP actuator members respectively farther from the apex such that a propagation-pulsing action of the heart is achieved.

"A rejection based on nonstatutory double patenting is based on a judicially created doctrine grounded in public policy so as to prevent the unjustified or improper timewise extension of the right to exclude granted by a patent...." See MPEP 804.II.B.1 and the cases cited therein. "A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s)....In determining whether a nonstatutory basis exists for a double patenting rejection, the first question to be asked is - does any claim in the application define an invention that is ... anticipated by, or is ... merely an obvious variation of ...an invention claimed in the patent?" *Id.*

It can be immediately seen that there is no conflict, in the sense of double patenting, between the appealed claims and those of the copending application. For example, the claims of the present invention are directed to a covering member (e.g., a garment) which is placed external to the human body, whereas Serial No. 10/373,940 is directed to a compressor that is adapted to be placed adjacent to an epicardial wall of the heart.

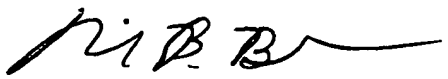
CONCLUSION

The references relied on by the Examiner do not support a *prima facie* case of obviousness against any of the appealed claims. The claims in the copending application no longer read on the present invention, and the latter would not have been obvious from the former. Thus, it is respectfully submitted that reversal of the rejections of record is in order.

FEES

The Office is authorized to charge any fees due and owing in respect to the filing of this paper to deposit account number 50-1047.

Respectfully submitted,



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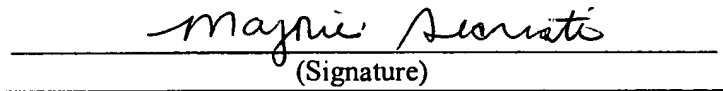

(Signature)

VIII. CLAIMS APPENDIX

1. (Previously presented) A system for exerting a compressive force on an exterior treatment portion of a user's body in synchrony with the heart beat of the user, comprising:

a covering member for covering the treatment portion; and

an electroactive polymer (EAP) actuator operably connected to the covering member, wherein said electroactive polymer actuator comprises an electroactive polymer member, a counter electrode and an electrolyte-containing region disposed between the electroactive polymer member and the counter electrode.

2. (Original) The system of claim 1 wherein the EAP actuator is rigidly connected to the covering member.

3. (Original) The system of claim 2 wherein the EAP actuator is connected to the covering member by adhesive.

4. (Original) The system of claim 2 wherein the EAP actuator is stitched to the covering member.

5. (Original) The system of claim 2 wherein the EAP actuator is woven into the covering member.

6. (Original) The system of claim 1 and further comprising: a controller operably coupled to the EAP actuator to provide a drive signal to drive actuation of the EAP actuator.

7. (Original) The system of claim 6 wherein the covering member is flexible such that actuation of the EAP actuator drives deformation of the covering member.

8. (Original) The system of claim 7 and further comprising: a heart sensor sensing a sinus rhythm of the heart and providing a heart sensor signal indicative of the sinus rhythm.

9. (Original) The system of claim 8 wherein the controller is configured to provide the drive signal based on the heart sensor signal.

10. (Original) The system of claim 9 and further comprising: a feedback component sensing a feedback characteristic and providing a feedback signal indicative of the sensed feedback characteristic.

11. (Original) The system of claim 10 wherein the controller is configured to provide the drive signal based on the feedback signal.

12. (Original) The system of claim 11 wherein the feedback component comprises: a metabolic sensor sensing a metabolic characteristic and providing the feedback signal based on the metabolic characteristic.

13. (Original) The system of claim 11 wherein the feedback component comprises: a blood flow sensor.

14. (Original) The system of claim 11 wherein the feedback component comprises: a blood pressure sensor.

15. (Original) The system of claim 1 wherein the covering member comprises a garment.

16. (Original) The system of claim 6 wherein the controller is configured to provide the drive signal to exert counterpulsation force on the treatment portion.

17. (Original) The system of claim 1 and further comprising: a plurality of EAP actuators operably connected to the covering member.

18. (Previously presented) A counterpulsation apparatus, comprising: a garment; and an electroactive polymer (EAP) actuator connected to the garment, wherein said electroactive polymer actuator comprises an electroactive polymer member, a counter electrode and an electrolyte-containing region disposed between the electroactive polymer member and the counter electrode.

19. (Original) The counterpulsation apparatus of claim 18 and further comprising: a plurality of EAP actuators connected to the garment.

20. (Original) The counterpulsation apparatus of claim 19 wherein the garment is formed of a fabric material.

21. (Original) The counterpulsation apparatus of claim 20 wherein the plurality of EAP actuators are woven into the fabric material.

22. (Original) The counterpulsation apparatus of claim 20 wherein the plurality of EAP actuators are stitched to the fabric material.

23. (Original) The counterpulsation apparatus of claim 20 wherein the plurality of EAP actuators are connected to the fabric material with adhesive.

24. (Original) The counterpulsation apparatus of claim 19 wherein the garment comprises multiple layers of fabric material and wherein the plurality of EAP actuators are disposed between the layers.

25. (Previously presented) A method of exerting pressure on an external treatment area of a patient, comprising: providing a garment to cover the treatment area; and actuating electroactive polymer (EAP) actuators connected to the garment in synchrony with the heart beat of the user, wherein said electroactive polymer actuators comprise an electroactive polymer member, a counter electrode and an electrolyte-containing region disposed between the electroactive polymer member and the counter electrode.

26. (Original) The method of claim 25 and further comprising: sensing a heart beat of the patient and providing a heart beat sensor signal indicative of the sensed heart beat.

27. (Original) The method of claim 26 and further comprising: actuating the EAP actuators to

exert counterpulsation pressure based on the heart beat sensor signal.

28. (Original) The method of claim 27 and further comprising: sensing a biological characteristic indicative of an efficaciousness of the counterpulsation pressure and providing a biological sensor signal indicative of the sensed characteristic.

29. (Original) The method of claim 28 wherein actuating the EAP actuators comprises: actuating the EAP actuators based on the biological sensor signal.

30. (Previously presented) The system of claim 1, wherein the electroactive polymer actuator comprises a conducting polymer.

31. (Previously presented) The system of claim 1, wherein the electroactive polymer actuator comprises a conducting polymer selected from polyaniline, polypyrrole, polysulfone, polyacetylene and combinations thereof.

32. (Previously presented) The counterpulsation apparatus of claim 18, wherein the electroactive polymer actuator comprises a conducting polymer.

33. (Previously presented) The counterpulsation apparatus of claim 18, wherein the electroactive polymer actuator comprises a conducting polymer selected from polyaniline, polypyrrole, polysulfone, polyacetylene and combinations thereof.

34. (Previously presented) The method of claim 25, wherein the electroactive polymer actuators comprise a conducting polymer.

35. (Previously presented) The method of claim 25, wherein the electroactive polymer actuators comprise a conducting polymer selected from polyaniline, polypyrrole, polysulfone, polyacetylene and combinations thereof.

IX. EVIDENCE APPENDIX

None.

X. RELATED PROCEEDINGS APPENDIX

None.